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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/441,443	05/15/95	HOUGHTON	M [illegible]24

18M1/0724

ALISA A HARBIN
CHIRON CORPORATION
INTELLECTUAL PROPERTY - R440
P O BOX 8097
EMERYVILLE CA 94662-8097

EXAMINER	
ZEMAN, M	
ART UNIT	PAPER NUMBER
1811	8

DATE MAILED: 07/24/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/21/97.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire — 3 — month(s), ~~or thirty days,~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 10 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of Reference Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

-- SEE FFICE ACTION ON THE FOLLOWING PAGES --

* U.S. GPO: 1996-410-238/40

DETAILED ACTION

1. Claim 10 is pending in this application.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Applicant's arguments filed 4/21/97 have been fully considered but they are not persuasive.

4. In view of amendments made to the pending claim, the following rejections are withdrawn:

The rejection of claim 10 under 35 U.S.C. 112, second paragraph, is withdrawn as the claim no longer recites the objectionable language.

5. Claim 10 is again provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 10 of copending Application No. 08/440,755. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. This rejection will be maintained until such time as these claims are amended or canceled such that they no longer claim the same invention.

6. Claim 10 is again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth in the previous office action.

The specification, as filed, does not demonstrate the isolation and/or purification of HCV virions. The specification details the binding of various HCV polypeptides by HCV-specific antibodies. These results are *not necessarily* indicative of isolated intact virions. The pages referenced in the specification are drawn to potential cell types in which HCV "could" replicate.

7. Claim 10 is again rejected under 35 U.S.C. 102(b) as being clearly anticipated by Prince and under 35 U.S.C. 102(e) as being anticipated by any of Seto, Seto, Coursaget, or Wands for the reasons set forth in the previous office action.

Applicant argues that none of the references purporting to have isolated NANB hepatitis virions, actually had the virus now known as HCV. Applicant states differences in particle size, density, associated activities and reservoirs within the body of the patient. While it is true that many, if not all of those characteristics are different between the instant invention and the prior art, it is noted that such identifying characteristics are *not* listed within the pending claim as amended. Applicant correctly points out that the prior art contains many confusing and conflicting theories as to the etiologic agent of NANB hepatitis. In the face of such confusion, identifying characteristics are necessary in the claims, in order to distinguish the claimed virus from the viruses described in the prior art. The Patent Office does not have the facilities to test all of the deposited viruses of the art of record. It is incumbent upon Applicant to differentiate the claimed invention over the prior art. It is noted that Coursaget lists four separate viral preparations that had been deposited. The '474 patent issued in 1984, the invention being the isolation of a virus associated with ptNANBH. As the patent issued in 1984, a date *after* the

references cited in the response of Gerety 1981, and Deinstag 1983 it would appear the Applicant doubts the validity of this US Patent. Applicant also compared the characteristics of the Coursaget virus to later published findings of other laboratories. There is no direct comparison to the claimed isolated virus of the instant invention. As set forth above, this application does not disclose the isolation and virological characteriztion of NANBV particles, resulting in the inability to distinguish the invention as now claimed over the art of record.

The virus used by Prince, the Hutchinson strain, *has* turned out to be HCV. The Hutchinson inoculum was first characterized by Feinstone in 1981. A recent study by Hilfenhaus uses the HCV strain H- which is the Hutchinson inoculum. (Hilfenhaus 1992 J Gen Virol 73:1015)

It is noted that Wands (US Patent 4,870,026) does indeed speak to the identification and isolation of Non-A non-B hepatitis viruses. "The NANB virus can be characterized and identified by at least four different characteristics... Physical-Chemical characteristics (size shape and protein sizes)... Immunological characteristics (non reactivity with HAV, HBV, EBV, CMV etc.)... Genetic characteristics (hybridization of genomic nucleic acids)... and Infectivity characteristics..." columns 5-7 of the '026 patent.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee of $750 for a large entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. If a notice of appeal and the appeal fee set forth in 37 CFR 1.17(e) were filed prior to or with the payment of the fee set forth in 37 CFR 1.17(r), the payment of the fee set forth in 37 CFR 1.17(r) by applicant will be construed as a request to dismiss the appeal and to continue prosecution under 37 CFR 1.129(a). In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 8:00 am and 5:30 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311.

The fax number for this Art Unit is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

mkz
July 17, 1997

MICHAEL P. WOODWARD
PRIMARY EXAMINER
GROUP 1800